

## II. SUMMARY OF SAFETY AND EFFECTIVENESS

K960406

**Applicant Name & Address:** B. Braun Medical Inc., Cardiovascular Division, 13000 Hwy 55  
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**Date Prepared:** January 22, 1996

**Common or Usual Name:** Braun Hemostasis Introducer Kits

**Device Classification Name:** Catheter Introducer

**Substantial Equivalence:**

K895044*	Balkin Up & Over	Cook
K945396	Braun Fluoro-Tip™ Hemostasis Introducer Kits	B. Braun Cardiovascular

**Device Description:** Braun Hemostasis Introducer Kits consist of a hemostasis valve introducer sheath packaged with a corresponding dilator. One or more of the following accessories may also be packaged with the sheath/dilator; guidewire, and/or obturator. The introducer sheaths are available in both straight and contralateral curve versions. They will be available in 5 - 9 French sizes, in lengths from 30 - 60 cm in the curved version and 10 - 60 cm in the straight version. Each will be packaged with an appropriately sized dilator. Optional items to be kitted with the sheath and dilator include a guidewire, and/or obturator. The components, their materials and accessories, are similar to those previously cleared under Braun 510(k)s; K894446, K930057, K931743, K945396. and K950882.

**Statement of Intended Use:** The Braun Hemostasis Valve Introducer Kits are designed to facilitate percutaneous introduction of catheters into the vasculature while preventing the backflow of blood.

**Summary/Comparison of Technological Characteristics:**

Characteristic	Braun Hemostasis Introducer Kits	Cook Up & Over Balkin Contralateral- K895044	Braun Fluoro-Tip K945396
Available French Sizes	5 - 9 French	Curved versions 5.5, 6 & 7 fr Straight versions of the Check-Flo introducer sheaths are available in 4- 9 french	7 - 10 fr
Available Lengths	curved - 30 - 60 cm straight - 10 - 60 cm	curved - 40 cm straight - 7 - 13 cm	10 - 32 cm
Body Stock Design	Braided	non-braided	non-braided, double layer sheath
Sheath Material	peba	Teflon®	FEP (Teflon®)
Hub to Body Tensile	5 fr - 14.5 lbs avg 9 fr - 18.4 lbs avg	7.2 lbs avg	7 fr - 14 lbs avg
Shape Recovery	5 fr 85% recovery @ 5 sec 86% recovery @ 60 sec 9fr 85% recovery @ 5 sec 88% recovery @ 60 sec	72% recovery @ 5 sec 77% recovery @ 60 sec	Not applicable
Sheath Leak Test	No leaks at 100 psi	No leaks at 100 psi	Not performed
Gasket leak Test	No leaks at 6 psi	No leaks at 6 psi	No leaks at 10 psi
Kink Resistance	5 fr - No kinks at 170° 9 fr - Kinked at avg of 107°	Kinked at an avg of 76°	Not performed
Radiopacity	More visible than Cook	Less visible than Braun	Not compared against Cook